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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,963	10/24/2001	Robert Anthony Hirst	18377-0006	2781
7590 09/17/2004			EXAMINER	
William L. Warren SUTHERLAND ASBILL & BRENNAN LLP 999 Peachtree Street, NE Atlanta, GA 30309-3996			GUCKER, STEPHEN	
			ART UNIT	PAPER NUMBER
			1647	

DATE MAILED: 09/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/045,963	Applicant(s) HIRST ET AL.	
	Examiner Stephen Gucker	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-31 is/are pending in the application.
- 4a) Of the above claim(s) 1-16 and 21-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17-20 is/are rejected.
- 7) ☒ Claim(s) 17-20 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1/14/03, 2/19/03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's election with traverse of Group III, claims 17-20, filed 8/2/04 is acknowledged. The traversal is on the ground(s) that no serious search burden exists for the Examiner because four of the seven inventive groups belong to the same U.S. patent class and subclass. This is not found persuasive because in addition to the U. S. patent literature, a great deal of non-U.S. patent and non-patent literature must be searched which do not use the U.S. patent classification system. Furthermore, in addition to anticipatory or obviousness prior art issues, the distinct inventive groups require searching the prior art for consideration of complex enablement issues as some of the inventive groups concern genetically modified neuronal cells, transgenic animals, and genetic therapy on humans, and the searches in these areas for either prior art or enablement issues would not overlap and indeed would be unduly burdensome on the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Australia on 10/24/00. It is noted, however, that applicant has not filed a certified copy of the patent application as required by 35 U.S.C. 119(b).

3. Claim 17 (and therefore claims 18-20 as well) is (are) objected to as being dependent upon non-elected claims. Appropriate correction is required.

Art Unit: 1647

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 17-20 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claims as written encompass products of nature which do not show the hand of man because the product by process limitations of the instant claims do not appear to distinguish partially or terminally differentiated neuronal cells as recited in the instant claims from partially or terminally differentiated neuronal cells that arise from stem cells *in vivo* in many animal species. The grounds of this rejection could be obviated by amending the claims to recite an isolated or purified partially or terminally differentiated neuronal cell.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 17-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (PTO-1449 filed 1/14/03, reference AG, "Lee"). Lee teaches a terminally differentiated (action potential producing) tyrosine hydroxylase (TH) positive dopaminergic neuronal cell with axon-like projections that was derived from murine embryonic stem cells (ES), meeting all the claim limitations of non-elected claim 1 upon which all the rejected claims depend from. See abstract, pages 675-677, and Figures 2-4 of Lee.


7. No claim is allowed.
8. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technical Center 1600 general number which is (571) 272-1600.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (571) 272-0883. The examiner can normally be reached on Monday to Friday from 0930 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached at (571) 272-0961. The fax phone number for this Group is currently (703) 872-9306.



Stephen Gucker

September 16, 2004



BRENDA BRUMBACK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600